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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/808,555	03/14/2001	Akira Takashima	A33865/090495.0233	3921

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EXAMINER

EWOLDT, GERALD R

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 05/29/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/808,555

Applicant(s)
Takashima et al.

Examiner
G.R. Ewoldt, Ph.D.

Art Unit
1644



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12/23/02 and 3/12/03.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 44-48, 65-69, 121, and 133 is/are pending in the application.
- 4a) Of the above, claim(s) 67 and 68 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 44-48, 65, 66, 69, 121, and 133 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 2 6) ☐ Other: _____

DETAILED ACTION

1. Applicant's election of Group IX, in Paper No. 7, filed 12/23/02, with traverse, is acknowledged. Applicant traverses the restriction on the grounds that Groups IX and X should be examined together. Applicant is advised that Groups IX and X have been rejoined.

2. Applicant's election of the species: MIP-3 β , in Paper No. 9, filed 3/12/03, is acknowledged. Because Applicant did not distinctly and specifically point out the supposed errors in the species requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Note that Applicant indicates in Paper No. 9, filed 3/12/03, that Claim 54 properly belongs in the elected Group. However, Claim 54 was canceled in Paper No. 7, filed 12/23/02, accordingly, said claim cannot be examined.

The restriction and species requirements are still deemed proper and are therefore made FINAL.

3. Claims 67 and 68 are withdrawn from further consideration by the Examiner, under 37 C.F.R. § 1.142(b) as being drawn to a nonelected species.

Claims 44-48, 65, 66, 69, 121, and 133 are being acted upon.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 69 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the term "MIP-3y" is vague and indefinite as the term is not defined in the specification. Accordingly, the metes and bounds of the claim cannot be determined.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 44-48, 65, 66, 69, 121, and 133 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,817,343 (1998) in view of Kim et al. (1998, IDS).

The '343 patent teaches a method for providing an artificial chemotactic factor gradient *in vivo* comprising administering an ethylene-vinyl-acetate (see particularly column 7, line 9) device (see particularly column 1, line 18), subcutaneously (see particularly column 11, line 41), said device comprising a chemotactic factor, said factor comprising a chemokine (see particularly column 4, line 63), and that said administration is useful for the controlled or sustained release of drugs (see particularly column 1, lines 5-15).

The reference teaching differs from the claimed invention only in that it does not teach the chemokine MIP-3 β .

Kim et al. teaches that MIP-3 β is a strong chemoattractant for T cells and mature B cells (see particularly page 2418, column 2, paragraph 2).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to provide an artificial chemotactic factor gradient *in vivo* comprising administering an ethylene-vinyl-acetate device subcutaneously, said device comprising a chemotactic factor, said factor comprising a chemokine, as taught by the '343 patent, substituting the specific chemokine MIP-3 β , as taught by Kim et al. One of ordinary skill in the art at the time the invention was made would have been motivated to use the specific chemokine MIP-3 β in the device of the '343 patent because said chemokine is a strong chemoattractant for T cells and mature B cells and would thus prove useful in a controlled or sustained release device used in the treatment of any disease for which the attraction of T or B cells might prove useful, i.e., essentially any pathogen-mediated disease or cancer.

8. No claim is allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Thursday from 7:00 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1 at (703) 305-3014. The CM1 Fax Center telephone numbers are 703-872-9306 (before final) and 703-872-9307 (after final).



G.R. Ewoldt, Ph.D.
Primary Examiner
Technology Center 1600
May 27, 2003